

**SUMMARY OF THE
ON-SITE ASSESSMENT COMMITTEE MEETING
JUNE 27, 2001**

The On-site Assessment Committee of the National Environmental Laboratory Accreditation Conference (NELAC) met by teleconference on Wednesday, June 27, 2001 at 1:00 p.m. Eastern Daylight Time (EDT). The meeting was led by its chair, Mr. Alfredo Sotomayor of the Wisconsin Department of Natural Resources. A list of action items is given in Attachment A. A list of participants is given in Attachment B. *The purpose of the meeting was to address items of importance as identified in the committee's previously distributed meeting agenda.*

INTRODUCTION

Mr. Sotomayor called the meeting to order with a welcome of the committee's new member, Mr. Faust Parker. Mr. Sotomayor noted that Mr. Parker is a toxicologist and as such can bring new expertise to the On-site Assessment Committee. Mr. Parker noted that his laboratory had recently completed its on-site assessment and that he can offer comments from that perspective, as well.

Mr. Sotomayor also recognized the committee's departing member, Ms. Rosanna Buhl. He noted that Ms. Buhl had been a member of the On-site Assessment Committee since its inception and that her many valuable contributions to the committee were greatly appreciated. Mr. Sotomayor mentioned that Ms. Buhl had been instrumental in shaping Appendix A into its current format.

CHAIR'S VISION FOR THE COMMITTEE

Mr. Sotomayor also recognized Mr. William Ingersoll for his contributions as past committee chair and expressed his thanks for Mr. Ingersoll's assistance in the past weeks. He expressed his pleasure that Mr. Ingersoll will continue as a committee member. As the newly elected chair, Mr. Sotomayor shared his vision for the On-site Assessment Committee with its members. Noting that he wants to build on all that the committee has already accomplished, Mr. Sotomayor linked his vision to the "Four Cs" presented by Silkie Labie, NELAC Chair, at the Seventh NELAC Annual Meeting (NELAC 7) closing:

- Commitment
- Consistency
- Cooperation
- Communication

REVIEW OF COMMITTEE ACTION ITEMS FROM NELAC 7

Mr. Sotomayor led a review of the Action Items from the committee's face-to-face meeting at NELAC 7. The status of Action Items from the NELAC 7 is as follows:

- Chapter 3, Appendix A (accelerated implementation), and Appendix B (accelerated implementation), as modified at NELAC 7, were approved by voting members at the NELAC 7 voting session.

There was moderate discussion of whether the immediate implementation of Appendix B would cause any problems. Although no clarification of the mechanism by which accelerated implementation will be accomplished was given at NELAC 7, the committee was in general agreement that any mechanism under consideration would have little effect on the committee and that Appendix B would stand.

- Mr. Sotomayor will seek expertise outside the On-site Assessment Committee in regard to proposed microbiology technical training course groupings or subgroupings in Section 3.2.3.2 of the NELAC Standard.

There was moderate discussion of this issue. It is the committee's understanding of the issue that it relates to Scope of Accreditation. If an accrediting authority does not offer accreditation for some discipline group or subgroup, then NELAC should not require the accrediting authority's assessors to complete technical training in that area. The components of an accrediting authority's technical training course depend, therefore, upon the Scope of Accreditation offered by the accrediting authority. It was suggested that the committee work in tandem on microbiology subgroupings and clarifying language for the standard. Although Mr. Sotomayor asked for volunteers to draft the subgroupings, it was agreed that limited committee experience in microbiology necessitates enlisting the help of experts outside the committee.

- The committee deferred discussion of expanded language on "Data and Document Review" in Appendix A Section A.4.5 until a future teleconference.

In discussion of this Action Item, Mr. Sotomayor reminded committee members of past committee discussions concerning basic assessor training in which it was suggested that data and document review be handled by following a simple procedure, such as pH, through the review process. Mr. Sotomayor suggested that Mr. Richard Sheibley had taken the lead on this suggestion. Since Mr. Sheibley was not present on the teleconference, Mr. Sotomayor asked committee members to review Section A.4.5 for future discussion.

- The committee deferred review of confidential business information (CBI) language in Chapter 3 Section 3.4.5 to be addressed when the committee undertakes revision of Appendix C for presentation at the Seventh NELAC Interim Meeting (NELAC 7i).
- The committee deferred review of Chapter 3 Section 3.7.4 to parallel the Appendix C section on "Assessment Reporting" to be addressed when the committee undertakes revision of Appendix C for presentation at NELAC 7i.
- The committee deferred discussion of continued development of Appendix C until a future teleconference in which the committee will address revision of the appendix for presentation at NELAC 7i.

OTHER COMMITTEE ACTION ITEMS

Mr. Sotomayor encouraged committee members to contribute Action Items not identified at NELAC 7. The committee named the following additional Action Items:

- Ensure that Chapter 3 is consistent with the other chapters of the NELAC Standard
- Update the Chapter 5 assessment checklist to reflect recent changes to the standard
- Develop a list of minimum elements that will be reviewed during an on-site assessment

The committee agreed to start a dialogue with the Accrediting Authority Workgroup to reach consensus on the minimum elements to consider during on-site laboratory assessments. It was noted that the committee must consider as a key issue how thorough document review must be to determine the ability of a laboratory to produce data of known and documented quality. It was suggested that an assessment checklist could be used as a guidance document in this regard.

There was moderate committee discussion of the concept of an initial representative review followed by an in-depth review if problems are identified. Noting that “representative” is a subjective word and that the language in the standard must be clear and unambiguous, the committee wrestled with how this concept may be incorporated into the standard. Mr. Sotomayor noted that the issue dovetails nicely with the task of the Accrediting Authority Workgroup to develop a standard operating procedure (SOP) for on-site assessments. He reemphasized that it is important for the committee to communicate with the Accrediting Authority Workgroup so all parties are in synchrony and they are not at cross-purposes. Mr. Sotomayor indicated that he would contact Mr. Richard Sheibley and Dr. Ken Jackson to determine if the Accrediting Authority Workgroup has already addressed this issue. The On-site Assessment Committee will move forward from that point without duplicating the effort of the Accrediting Authority Workgroup.

APPENDIX D

Mr. Sotomayor shared his recollection of the reception of Appendix D by NELAC stakeholders at NELAC 7. He noted that some stakeholders had questioned whether Appendix D is necessary. There was subsequent discussion of whether the appendix is meeting its intended purpose. The committee shared two examples from Appendix D as follows:

Section D.1 (Introduction) - A committee member questioned how reviewing a test method can tell an assessor if the laboratory has a good quality system. While reviewing the execution of the method tells an assessor about the laboratory’s quality system, that is not the same as reviewing the SOP for a test method. Committee members noted that participants at NELAC 7 had two perspectives regarding how one evaluates a test method: review the SOP and determine if it is adequate; or review the SOP, determine if it is adequate, and then determine if the laboratory is following the SOP.

Section D.2 (Evaluation Phases) - It was noted that the language of this section implies that an assessor must complete every item under each of the three evaluation phases. This was not the committee's intent in drafting the language.

There was moderate discussion on the advisability of obtaining SOPs for review prior to the on-site assessment. A committee member expressed two concerns with obtaining SOPs in advance. If the assessor asks for the laboratory's entire SOPs, then the assessor must handle a lot of paper. If the assessor asks for just a few selected SOPs, then the laboratory is put on notice that the assessor considers only a few SOPs to be important. The committee member suggested that the assessor would be more effective selecting a sampling of the laboratory's SOPs onsite.

In further discussion, the committee concluded that Appendix D is needed, that the appendix requires additional work, and that the committee must be clear about but its purpose in order to revise it. It was suggested that Chapter 5 identifies the systems the laboratory must have to ensure that its data is of known and documented quality. It was further suggested that Appendix D must spell out how an assessor must review what the laboratory has done to ensure its data is of known and documented quality. In other words, Appendix D must look at Chapter 5 from an assessor's point of view and provide guidance on what the assessor must do to determine that a laboratory is in compliance with Chapter 5. It was also noted that the common problem is not that laboratories do not have compliant SOPs. The common problem is that laboratories are not following their SOPs.

Mr. Santos Urrea shared anecdotal evidence related to his experience with assessors as a representative of a municipal laboratory and Mr. Parker shared anecdotal evidence related to his recent assessment experience as a representative of a commercial laboratory. In closing, it was suggested that the committee take a fresh look at the appendix based on a review of its title, which addresses:

1. Critical performance elements of test methods (related to Chapter 5)
2. Assessment procedures (related to the committee's current discussion)

APPENDIX C

Ms. Mimi Uhlfelder indicated that she is willing to continue to lead the effort on the development of Appendix C. She noted that CBI was identified at NELAC 7 as a major issue in that states may be bound by state regulations rather than federal regulations. She also noted that Mr. Sheibley had posed a question in regard to CBI. Ms. Uhlfelder indicated that she will contact Mr. Sheibley to get clarification of his question.

FUTURE MEETINGS

Mr. Sotomayor informed committee members that NELAC 7i will be held December 3-7, 2001 in Arlington, VA. Three training workshops will be offered on the weekend before the meeting.

The committee's next meeting will be on July 18, 2001 via teleconference. Ms. Uhlfelder indicated that she would be unable to participate in the teleconference.

CONCLUSION

The committee's allotted teleconference time having expired, Mr. Sotomayor thanked everyone in attendance for their input. The meeting was adjourned at 2:30 p.m. EDT.

**ACTION ITEMS
ON-SITE ASSESSMENT COMMITTEE MEETING
JUNE 27, 2001**

Item No.	Action	Date to be Completed
1.	Mr. Sotomayor will investigate mechanisms for recognizing departing committee members for their contributions to the committee.	7/18/01
2.	Mr. Sotomayor will contact individuals outside the On-site Assessment Committee with expertise in microbiology to draft subgroupings for technical training (Section 3.2.3.2).	7/18/01
3.	Committee will include discussion of expanded language on “Data and Document Review” (Appendix A Section A.4.1.1.2.3, item 5) on their agenda for a future meeting.	7/18/01
4.	Committee will continue development of Appendix C in response to comments received at NELAC 7, with consideration of the following: 1) Expanded language on “Data and Document Review” – specifically issue of whether accrediting authority must communicate preliminary findings to the laboratory (Pre-assessment Section 3) 2) Review of CBI language in Chapter 3 Section 3.4.5 to ensure consistency with Appendix C (Ms. Uhlfelder to contact Mr. Sheibley for clarification on this issue) 3) Review of Chapter 3 Section 3.7.4 to parallel the Appendix C section on Assessment Reporting (release to national database).	8/15/01
5.	Committee will review Chapter 3 to ensure consistency with other chapters of the NELAC Standard.	10/3/01
6.	Committee will update Chapter 5 assessment checklist to reflect recent changes to the NELAC Standard.	TBD
7.	Mr. Sotomayor will contact Dr. Jackson and Mr. Sheibley to open dialogue on developing a list of minimum elements that will be reviewed during an on-site assessment.	7/18/01
8.	Committee will continue development of Appendix D in response to comments received at NELAC 7.	10/3/01
9.	Committee will meet via teleconference.	7/18/01

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ON-SITE ASSESSMENT COMMITTEE MEETING
JUNE 27, 2001**

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